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March 5, 2003

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Via Electronic and U.S. Mail

Stuart Shapiro  
Office of Information and Regulatory Affairs  
Office of Management and Budget (OMB)  
New Executive Office Building  
Room 10235  
725 17th St. NW  
Washington, DC 20503

**Re: SPI Comments on Paperwork Burden with Respect to FDA's Proposed Regulation on Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Docket No. 02N-0276]**

Dear Mr. Shapiro:

The Society of the Plastics Industry, Inc., (SPI)<sup>1</sup> by its attorneys and through its Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC), hereby respectfully submits these comments with regard to the regulation proposed by the Food and Drug Administration (FDA) entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," which was published in the *Federal Register* on February 3, 2003 (68 *Fed. Reg.* 5377). This notice requested public comment on the paperwork burden with regard to the implementation of the provision for registration of facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. This provision is contained in the Public Health Security and Bioterrorism Preparedness

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<sup>1</sup> Founded in 1937, The Society of the Plastics Industry, Inc. is the trade association representing the fourth-largest manufacturing industry in the United States. SPI's 1,500 members represent the entire plastics industry supply chain, including processors, machinery and equipment manufacturers, and raw material suppliers. The U.S. plastics industry employs 1.5 million workers and provides \$330 billion in annual shipments. The Food, Drug, and Cosmetic Packaging Materials Committee is composed of SPI members with particular interest and expertise in packaging for food and other FDA-related products. The Committee has a long history of working cooperatively with FDA on regulatory issues relating to packaging.

and Response Act of 2002 (the "Bioterrorism Act"). Section 305, Pub. L. 107-188 *amending* Federal Food, Drug, and Cosmetic Act (FFDCA) (codified at 21 U.S.C. 331 *et seq.* (2002)).

SPI commends Congress and the Food and Drug Administration for taking actions to protect the U.S. food supply from terrorist acts, and encourages the Agency to continue working with industry to take reasonable steps to protect the public. However, as explained more fully below, we respectfully submit that FDA's proposal to extend the registration requirement to facilities that manufacture, process, pack, or hold packaging or other food-contact articles will unduly burden industry. This burden also is in contravention of Congressional intent.

With regard to the Paperwork Reduction Act of 1995, FDA specifically invited comments on: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information would have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. SPI will comment on (1) and (2) as they pertain to the industries that provide food packaging and other food-contact articles. We are very hopeful that these comments and subsequent comments to FDA will result in the proposed regulations being revised so as not to apply to food-contact articles. In our view, there are no methods to improve the collected information or the mechanism for collecting the information that would justify requiring registration of facilities that manufacture or handle food packaging (not already containing food) or food-contact articles.

- (1) Is the proposed collection of information necessary for the proper performance of FDA's functions, including whether the information would have practical utility?**

SPI's FDCPMC opposes the registration requirement with respect to food-contact materials (not yet containing food) and asserts that the paperwork burden imposed on industry by this proposal should not be allowed because it is contrary to Congressional intent.

By way of background, FDA seeks to bring suppliers of food-contact materials (not yet containing food) within the reach of the proposed regulation by referring to the definition of "food" found in Section 201(f) of the FFDCA, which defines "food" as (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 21 U.S.C. § 321(f). Historically, FDA has relied on the FFDCA's definition of

“food,” in conjunction with its definition of “food additive”<sup>2</sup> to provide a basis for the Agency to assert regulatory authority over any food-contact materials that are also food additives. In this case, the proposed regulation includes a list of examples of products that FDA considers to be covered by the definition of “food,” and the list identifies “substances that migrate into food from food packaging and other articles that contact food” as “food” for purposes of the regulation.

FDA has attempted to clarify exactly which packaging materials would fall within this description. In this regard, FDA’s proposal states that ‘substances that migrate into food from food packaging’ include “immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food.” The terms “immediate food packaging or components of immediate food packaging,” however, potentially cover a vast array of products, including plastic resins, glass, paper, metal, and rubber, and many other materials, such as colorants, lubricants, preservatives, antioxidants and emulsifiers that are used in food packaging.

During a February 12, 2003 meeting at the National Food Processors Association, FDA officials attempted to clarify further which packaging would be subject to the registration requirement, and specifically indicated that the intent of the proposal is for the rule to cover only finished packaging that will be in direct physical contact with food. An example used by FDA was that the regulation would apply to liners for cereal boxes, but not the boxes. In response to a question, FDA indicated that the regulations would not cover polymers, additives, or monomers, but only the “immediate” food packaging made from such components. We assume from FDA’s statement that this regulation also was not really intended to apply to the many other components of food packaging, some of which are identified above. The current language in FDA’s proposal, however, extending as it does to “components of immediate food packaging,” does not limit the coverage of the regulation as FDA apparently intends. The meaning of “immediate food packing” is even unclear since it could include only the final, completely formed packaging, or also the film or sheet or other bulk materials from which the final packaging is formed.

Contrary to FDA’s declaration of intent, however, the proposed registration regulation is not even limited by its terms to packaging, much less to finished packaging. The Agency’s definition of “food” would extend to “substances that migrate into food from food packaging **and other articles that contact food.**” (Emphasis added). We assume that FDA really means to require registration of facilities dealing with the articles from which migration occurs, not the

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<sup>2</sup> Section 201(s) of the FFDCA defines, in part, “food additive” to include “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food.” 21 U.S.C. § 321(s). The definition specifically includes substances intended for use in packing or packaging food. *Id.*

migrating substances themselves. Leaving aside that ambiguity, however, still leaves the apparent requirement for registration of facilities that manufacture, store, or otherwise handle food-contact articles other than packaging, such as food processing equipment and glassware, dishware, cutlery, kitchen appliances (and other "houseware" items). If the regulation continues to read this broadly, it will impose a significant paperwork burden on a large number of companies.

The breadth of the language in the proposed regulation with respect to food-contact materials is contrary to the intent of Congress as evidenced by the language of the underlying statute itself. With regard to the registration requirement, the Bioterrorism Act states that facilities that "manufacture, process, pack or hold **food for consumption** in the United States" will be required to register (emphasis added). We consider the term "food for consumption" to be properly interpreted as referring to edible food, not food-contact articles. Based on discussions with Congressional staff and others as the legislation was under consideration, we are quite certain that there was never any intent for the registration provision to extend to facilities dealing with food-contact articles. In the case of this provision (unlike the import notification provision discussed in separate comments filed along with these), Congress did not provide legislative history confirming its intent with respect to food-contact materials. We are confident, however, that the absence of such statements of intent derives from the assumption by Congress that nobody would misconstrue the meaning of "food for consumption."

Another indication that Congress did not have food-contact articles in mind as triggering facilities registration under the Bioterrorism Act is the legislators' reference to the food categories in 21 C.F.R. § 170.3. The Bioterrorism Act states that FDA may require each facility to submit the general food category, as identified under § 170.3, of the food manufactured, processed, packed, or held at the facility. Indeed, FDA has proposed to include the categories from § 170.3 as a mandatory field on the registration form. However, § 170.3 does not include categories for food-contact materials.

Additionally, including food-contact materials in the regulation will impose burdens on the industry that are disproportionate to any minimal reduction in risk and will provide no significant protection against terrorism. Regardless of whether or not the registration requirement would apply only to finished food packaging, it would impose a significant burden on the companies involved. The requirement would apply not just to the facilities that manufacture the products, but also the warehouses where they are stored. Large companies, particularly multinationals, will have to spend an inordinate amount of time simply identifying the facilities that will need to be registered and putting in place mechanisms for meeting their obligations, including the updates FDA proposes to require.

Not only would registration of all of these facilities be exceedingly burdensome, but the information would have limited usefulness in satisfying the purpose of the Bioterrorism Act, which is to "expand FDA's powers to prevent and respond effectively to terrorist threats against the food supply." FDA does not explain how registration of the facilities that manufacture and

store food-contact materials would deter the intentional contamination of food or assist the Agency in determining the source and cause of contamination. In estimating the benefits of the proposed regulation, FDA discusses five outbreaks of foodborne illness from accidental and intentional contamination of edible food, but there is no mention of food-contact articles being related to any such occurrences. Further, requiring registration of food-contact materials would divert FDA attention and resources from activities directed toward more immediate food security risks.

**(2) Is FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used, accurate?**

FDA's assessment of the number of domestic companies that might need to register in connection with food packaging materials probably is overly inclusive if FDA's true intent is to include only finished packaging since the estimate includes companies supplying basic chemicals. These products may fit within the FFDCA definition of food, but they are not finished packaging.

With respect to foreign firms, however, FDA relies entirely on its proprietary OASIS database, which we do not believe includes many, if any, suppliers of food-contact articles. We expect that the number of foreign suppliers of food-contact materials required to register will be much larger than FDA's estimate.

Furthermore, FDA's cost calculation ignores the effort, discussed above, that will be required of large companies to identify all of the manufacturing and handling facilities covered by the registration requirement. As an example, we have been informed by one large supplier of food packaging materials that approximately 1, 000 of its facilities may need to be registered, depending on how FDA defines the products that trigger the registration requirement. With such a large number of facilities affected, both identifying the facilities and managing the submission of change notices would require programming of the company's computer system and a significant commitment of personnel and other resources.

Finally, past experience with other similar situations has shown that a significant number of food processors will require packaging suppliers to certify that their facilities have been registered properly with FDA, thereby increasing the administrative burden on these companies. This cost also is not included in FDA's cost calculation.

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In summary, the burden of registering facilities that manufacture and store food-contact materials is contrary to the language and intent of the Bioterrorism Act. In addition, such registration will not provide any significant assistance to FDA in deterring or responding to terrorism directed against the food supply. If FDA nevertheless continues to propose inclusion of some food-contact materials within this proposed regulation, the scope of the products to be covered must be clarified before the paperwork burden can even be estimated.

Stuart Shapiro  
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**KELLER AND HECKMAN LLP**  
LAW OFFICES

SPI's FDCPMC appreciates this opportunity to comment on the paperwork burden that would be imposed by FDA's proposal.

Sincerely,



Ralph A. Simmons  
Legal Counsel for  
The Society of the Plastics Industry, Inc.